

1 RECORD OF ORAL HEARING

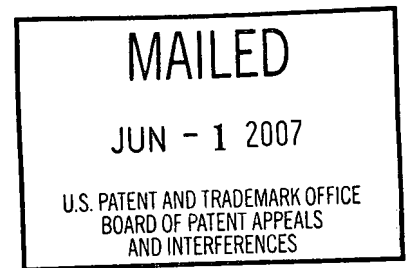
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3 UNITED STATES PATENT AND TRADEMARK OFFICE

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6 BEFORE THE BOARD OF PATENT APPEALS
7 AND INTERFERENCES
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10 Ex parte RICHARD J. LAZZARA, THOMAS S. HEYLMUN
11 and KEITH D. BEATY
12

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14 Appeal 2007-0192
15 Application 09/237,605
16 Technology Center 3700
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19 Oral Hearing Held: May 15, 2007
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23 Before MURRIEL CRAWFORD, JENNIFER BAHR, and LINDA
24 HORNER Administrative Patent Judges
25

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27 ON BEHALF OF THE APPELLANT:

28
29 MARK N. ANDERSON, ESQUIRE
30 Jenkins & Gilchrist, PC
31 225 West Washington
32 Suite 2600
33 Chicago, Illinois 60606
34

35 The above-entitled matter came on to be heard on May 15, 2007,
36 commencing at approximately 2:03 p.m., at the United States Patent and
37 Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Victoria
38 L. Wilson, Notary Public.

1 THE USHER: Calendar Number 31. Appeal Number 2007-0192.

2 Mr. Anderson.

3 JUDGE CRAWFORD: Good afternoon, Mr. Anderson.

4 MR. ANDERSON: Good afternoon.

5 JUDGE CRAWFORD: We have had a chance to talk about the case
6 briefly. Begin.

7 MR. ANDERSON: Did you say to begin? I'm sorry.

8 JUDGE CRAWFORD: Yes, you can begin.

9 MR. ANDERSON: Thank you.

10 The remaining claims pending in this appeal are both -- are all
11 rejected under section 103 based on two references, the Haruyuki reference
12 and the Niznick reference. There are clear shortcomings with the rejections
13 in this case.

14 To begin with the Haruyuki reference. The examiner says that the
15 Haruyuki reference discloses a surface that's inherently the same as the acid-
16 etched surface produced by the claims of the pending application.

17 Haruyuki teaches to use a hydrofluoric acid and hydrogen peroxide
18 treatment to smoothen sharp edges and sharp spines after an initial acid
19 etching. Haruyuki further teaches that sharpness causes tissue irritation that
20 is problematic for a patient and can lead to diseases such as cancer based on
21 the sharpness.

22 Further, the photos of Haruyuki show clearly different surfaces than
23 those submitted in the declaration by Dr. Gubbi in this matter.

24 JUDGE HORNER: Does Haruyuki have irregularities that form,
25 though? Doesn't it disclose that the second treatment step is really just to

1 smooth the sharpened peaks, not to smoothen the entire surface?

2 MR. ANDERSON: Well, but basically, the surface -- the surface
3 roughness, as a whole, will be lowered by smoothing the peaks and the
4 spines that it teaches that the second step is done to accomplish.

5 JUDGE HORNER: But it will still have some peak to valley distance.

6 MR. ANDERSON: There will be some peak to valley distance, yes,
7 just the second step is to reduce that distance rather than to increase it as a
8 roughening step would do.

9 Turning next to the Dr. Gubbi declaration. The applicant surface is
10 clearly not obtained by the Haruyuki process if you review the photographs
11 attached in the Gubbi declaration. In fact, Dr. Gubbi could not even
12 replicate the results that Haruyuki claimed to have achieved in his patent
13 application.

14 JUDGE HORNER: In what sense? He couldn't get the peak to
15 valley? Because it wasn't clear from the declaration. He sort of said he was
16 comparing a particular implant that's a commercially available product --

17 MR. ANDERSON: Right.

18 JUDGE HORNER: -- to a number of different samples described in
19 Haruyuki.

20 MR. ANDERSON: Right.

21 JUDGE HORNER: And it wasn't clear to me, because the declaration
22 doesn't have peak to valley measurements, what the difference was.

23 MR. ANDERSON: I believe if you -- do you happen to have the
24 declaration --

25 JUDGE HORNER: Yes.

1 MR. ANDERSON: -- in front of you?

2 I believe if you look to, for instance, example 1 and example 2 of
3 Exhibit B, I believe it is, of the Gubbi declaration, you see both a scanning
4 electron microscope surface and a three-dimensional topographic surface as
5 well.

6 And if you compare those to osseotite surface, which is used --
7 formed by the -- or what would be the result of the claimed invention in this
8 product, in Exhibit A of the Gubbi declaration, you can clearly see that the
9 irregularities are not nearly as uniform in the comparative samples.

10 In fact, you can see that there are clear machining marks that interrupt
11 each layer of peaks, whereas in the osseotite surface, it is much closer to
12 being a uniform array of peaks and valleys. You don't have the linear
13 demarcation between rows of peaks and valleys.

14 JUDGE HORNER: Can you point me on this to what you are -- if
15 you can approach and just point to the exact 3-D graphs that you are
16 referring to.

17 MR. ANDERSON: Okay. So this -- this Exhibit A, this is the three-
18 dimensional graph of the -- I'm sorry -- of the -- of the product that's at issue
19 in the application. This is the osseotite surface.

20 Examples 1 and 2 from Gubbi declaration, this is -- these are two of
21 the procedures outlined in the Haruyuki reference for producing the surfaces.
22 And as you can see, you have very linear rows, and then in the second
23 reference, which was a shorter second etching, you can see that the
24 topography is much, much smoother than what is found in Exhibit A.

25 JUDGE HORNER: Okay. Thank you.

1 But Exhibit A, the osseotite example you used for comparison, I didn't
2 see in the -- I guess my problem there is it is one particular example that you
3 are comparing rather than comparing the prior art to the claim.

4 MR. ANDERSON: Well, the claim does recite that you have a
5 roughened region for facilitating osseointegration, said roughened region
6 being uniformly acid-etched with a second acid solution after a native oxide
7 layer had been removed by contact with a first acid solution with minimum
8 consumption of said titanium metal to produce a substantially uniform array
9 of irregularities having peak to valley heights not greater than about ten
10 microns.

11 We believe that that osseotite surface shown in that example clearly
12 fits within the language of claim 51. The other independent claims recite
13 similar limitations with the ten microns and uniform irregularities. So we --

14 JUDGE HORNER: But the second -- the example 2 appears to be
15 substantially uniform. It is just not as -- the peaks maybe aren't as high.

16 MR. ANDERSON: Which would be consistent with the teaching of
17 Haruyuki that there would be no -- that not -- that you smoothen with the
18 second step, not roughen.

19 We see Haruyuki as being fundamentally different than the
20 application and the claims pending in this appeal, as Haruyuki teaches that
21 you smoothen the surface after you have removed the native oxide layer,
22 whereas the present application teaches and recites and claims that you
23 roughen the surface after removing the native oxide layer.

24 JUDGE HORNER: But if Haruyuki's method results in peaks and
25 valleys, just not as large as what would result from the claimed -- from the

1 particular acid solution disclosed in your specification, why wouldn't it still
2 meet the claim?

3 Because the claim only requires the peak to valley heights be not
4 greater than about ten microns. So we have got uniform peak to valley in
5 Haruyuki, they are just not as large as if you had used the treatment method
6 in your disclosure.

7 MR. ANDERSON: Well, I think, additionally, we would say that it is
8 not a uniform array, as you still have machining marks present on the
9 surface. So their acid etching does nothing to the machining marks, and I
10 believe that Dr. Gubbi points that out in his declaration.

11 JUDGE HORNER: Is there anything in the specification you can
12 point me to that would help us define "substantially uniform"?

13 MR. ANDERSON: I don't believe that that term is defined.

14 Again, turning now to the teachings and the combination of Niznick
15 with Haruyuki. Niznick and Haruyuki teach away from combination.
16 Haruyuki teaches that depressions from a half micron to five microns are the
17 ideal for this application.

18 In fact, Haruyuki, as I previously mentioned, teaches that surface
19 roughness over five microns can cause tissue irritation which can lead to a
20 condition such as cancer which, obviously, no one skilled in the art would
21 want their patients to obtain cancer based on the products that they are
22 developing.

23 Niznick teaches a far rougher surface. In fact, Niznick claims require
24 that a portion of the implant have at least a 25-micron surface roughness,
25 which is five times greater than Haruyuki. Therefore, the teachings are

1 incompatible, in that Haruyuki teaches not to exceed 5 microns and Niznick
2 teaches to exceed 25 microns.

3 Further, Haruyuki teaches that a 25-micron surface roughness might
4 not even function, as Haruyuki teaches that any surface roughness over 10
5 micron is not good for adhesion of the bone, as the bone cells may be
6 smaller than 10 microns, and therefore, Haruyuki would lead one skilled in
7 the art to believe that Niznick might not even function and might cause
8 cancer in their patient.

9 JUDGE HORNER: But didn't the examiner rely on Niznick merely to
10 teach the standard components in a dental implant, the -- the head portion
11 and the threaded end?

12 MR. ANDERSON: The examiner relied on Niznick to teach the
13 various regions of coating are found on implants, but, however, when one is
14 making a 103 rejection, it is a requirement that the entire teaching of a
15 reference be considered, including teaching -- portions that teach away from
16 combination.

17 And if two references are incompatible based on their disclosures, an
18 examiner cannot use them as a basis for a 103 rejection, and that's federal
19 circuit law.

20 And Niznick additionally teaches that a coating of hydroxyl-apatite or
21 titanium plasma spray or a grit blast is used to create this very rough surface.

22 Haruyuki additionally teaches away from this in teaching that to avoid
23 adding excess materials, because of the possibilities of contamination, the
24 increased cost associated with these processes and the complexity that would
25 be required in order to form the Niznick surface or a surface where a coating

1 is applied or these other steps.

2 Therefore, one skilled in the art would not combine Haruyuki with
3 Niznick based on these dissimilar teachings.

4 Next, the Niznick reference itself. Niznick teaches that the lowermost
5 end of the threads should not be as rough as the central portion of the
6 implant itself.

7 Niznick teaches that the lower portion of the threads should have a
8 surface roughness of about 20 microns, which Niznick considers to be a
9 relatively smooth surface. Niznick then teaches that the middle portion
10 should have a roughness of at least 25 microns.

11 Claim 51 of the pending appeal recites that smooth head and a
12 uniform acid etched to the lower- most end with irregularities no greater
13 than 10 microns. Niznick considers 20 microns to be relatively smooth and
14 a 25-micron surface to be much rougher.

15 Therefore, Niznick, as a whole, teaches that what Niznick considers to
16 be relatively smooth is far -- is greater in roughness than anything that's
17 found in our claimed invention.

18 Similar arguments may be made for the other independent claims
19 pending in this application as the incompatibilities of combining Haruyuki
20 with Niznick based on the fact that they teach completely different things,
21 that Haruyuki -- one skilled in the art after reading Haruyuki would not be
22 motivated to combine at all with the teaching of Niznick.

23 Finally, the examiner failed to consider at all the declaration
24 submitted by Dr. Porter for secondary evidence of nonobviousness. The
25 commercial success of products containing the claimed apparatus have

1 increased greatly in sales after starting to have the features found in the
2 claims.

3 Paragraphs 3 and 5 of the Porter declaration use language that clearly
4 tracks with the claims of the pending application. The rapid increase in sales
5 shows a commercial success has been experienced by this product.

6 Therefore, we believe that the Haruyuki reference and the Niznick
7 reference are not combinable based on the fact that they teach one skilled in
8 the art completely disparate methods of surface roughening.

9 Haruyuki actually teaches a smoothened surface by a second
10 application of an acid and it is an acid mixed with hydrogen peroxide.
11 Further, Niznick teaches a much rougher surface than what Haruyuki
12 recommends.

13 The Niznick surface is so rough that Haruyuki first considers that it is
14 a roughness that could possibly cause cancer in a patient, and second,
15 considers it a roughness that's too rough to achieve proper bonding with the
16 bone as the pore size of the bone is possibly smaller than the surface
17 roughness.

18 Therefore, we believe that one skilled in the art would not combine
19 Haruyuki with Niznick. Further, the fact that Haruyuki teaches to smoothen
20 a surface with a second acid treatment rather than roughening the surface
21 clearly makes it dissimilar with the surface process disclosed and claimed in
22 the pending application.

23 Therefore, we believe that these claims are allowable and patentable
24 in light of the prior art cited against us.

25 JUDGE CRAWFORD: Okay. Thank you.

1 Whereupon, the proceedings at 2:18 p.m. were concluded.